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Signed

Dated 9 February 2004

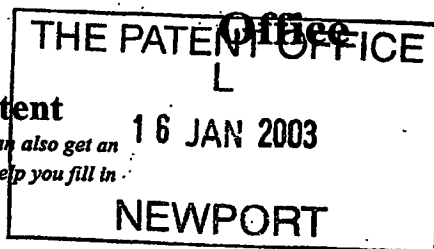
**Patents Form 1/77**

Patents Act 1977

(Rule 16)

**The  
Patent**

16JAN03 E777591-3 002396  
P01/7700 0.00-0300992.5



**Request for grant of a patent**

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

**The Patent Office**  
Cardiff Road  
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1. Your reference 11865:SF

2. Patent application number 116 JAN 2003 0300992.5  
(The Patent Office will fill in this part)

3. Full name, address and postcode of the or of each applicant (underline all surnames)  
Clinimed (Holdings) Limited  
Cavell House  
Knaves Beech Way  
Loudwater  
High Wycombe  
Buckinghamshire HP10 9QY

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

England

727 8563000

4. Title of the invention A Support for an Ostomy Bag

5. Name of your agent (if you have one) Saunders & Dolleymore

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

9 Rickmansworth Road  
Watford  
Hertfordshire  
WD18 0JU

Patents ADP number (if you know it)

1453001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country	Priority application number (if you know it)	Date of filing (day/month/year)
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7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing (day/month/year)
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8. Is a statement of inventorship and of right to grant a patent required in support of this request? (Answer 'Yes' if:

- a) any applicant named in part 3 is not an inventor, or
- b) there is an inventor who is not named as an applicant, or
- c) any named applicant is a corporate body.

Yes

**Patents Form 1/77**

9. Enter the number of sheets for any of the following items you are filing with this form.  
Do not count copies of the same document

Continuation sheets of this form

Description	6
Claim(s)	1
Abstract	1 DM
Drawing(s)	3 T3

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

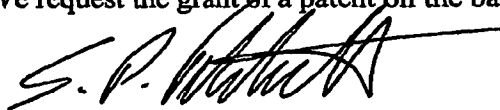
Statement of inventorship and right to grant of a patent (*Patents Form 1/77*) 3 ✓

Request for preliminary examination and search (*Patents Form 9/77*) 1 ✓

Request for substantive examination (*Patents Form 10/77*)

Any other documents  
(*please specify*)

11. I/We request the grant of a patent on the basis of this application.

  
Signature

Date  
15 January 2003

12. Name and daytime telephone number of person to contact in the United Kingdom  
Stuart Fitchett  
01923 238 311

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**Notes**

- a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- b) Write your answers in capital letters using black ink or you may type them.
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DUPLICATE

A SUPPORT FOR AN OSTOMY BAG

The present invention relates to a support for an ostomy bag, but is also applicable to wound drainage bags. For the purposes of the present specification, including the claims, all references to ostomy bags are to be interpreted to include wound-drainage bags and wound managers.

The main types of ostomy bags are colostomy bags, ileostomy bags and urostomy bags. These together with wound drainage or wound manager bags have in common that they form a seal around the stoma, or wound, through which waste material is drained from the body.

Ostomy bags comprise a receptacle for the waste having an aperture for receiving the waste. This aperture is normally surrounded by a flange of hydrocolloid adhesive. Hydrocolloid adhesive is particularly "skin friendly" comprising approximately 20% gelatine, 20% pectin and 20% carboxymethyl cellulose in an organic matrix of polyisobutylene, which comprises the remaining 40% of the hydrocolloid adhesive.

The proportions of the components of the hydrocolloid adhesive may vary, but an important property of the material is that it is breathable. This is important because a particular problem with ostomy bags arises from the extended periods for which they have to be worn by a patient, normally 24 hours a day. This commonly results in maceration where the skin cannot breath and becomes saturated.

The wear time of an ostomy bag is often limited by the seal about the flange failing, whereby waste fluids from the body may leak past the seal, requiring the wearer to replace the ostomy bag, thus replacing the seal formed with the bag. This leakage is not only unpleasant and potentially embarrassing for the wearer, but the waste is also corrosive to the skin when the skin is exposed to the waste for any significant period of time. This together with any maceration that may occur reduces the likelihood of any subsequent ostomy bag correctly sealing.

Increasing the flange size on an ostomy bag might be thought to improve the sealing ability of the flange, however it is not desired to provide an excessively large flange because this in turn will expose a larger area of skin to the possible risk of maceration and also cause problems due to the flexing of the body under the area of the flange.

Ostomy bags thus normally have a standard size of flange that is considered appropriate for the "average" wearer. However, all wearers are different and some find that the standard flange of an ostomy bag does not seal, or fails before the ostomy bag is full. This often arises where there are bony protuberances close to the stoma or where stomal hernias arise, often as a side effect of the skin being cut to form the stoma.

There are currently two products available to a wearer who suffers problems with leaking ostomy bags. The first is hydrocolloid strip, formed by extruding and rolling hydrocolloid material. The strip is cut to length by a wearer and applied in the area where the flange seal normally fails. An alternative product used by some ostomy bag wearers is sold under the trade mark "SECUPLAST". This comprises an annular disk of tape covered with an acrylic adhesive. This is placed behind and around the flange of an ostomy bag

thereby extending the flange. However, a problem with this material is the acrylic adhesive is not as "skin friendly" as the hydrocolloid material and tends to increase skin trauma, which in turn causes problems with the subsequent fitting of further ostomy bags.

According to the present invention there is provided a support for an ostomy bag comprising a layer of hydrocolloid shaped to fit around and extend a portion of a flange of an ostomy bag.

Employing the present invention enables a wearer to fit a support in accordance with the present invention to that portion of the flange of an ostomy bag that is most prone to fail, when fitted to that particular wearer. The shaping of the layer of hydrocolloid, to fit around and extend the flange, ensures a large section of the circumference of the flange is extended whilst minimising the additional area of skin covered.

The invention is particularly advantageous in that it permits a standard support or range of supports to be used with one or more standard ostomy bags.

The hydrocolloid is self-adhesive on one side and covered by release paper arranged to be removed prior to use. This permits the hydrocolloid to be correctly positioned partially behind the flange and the release paper removed, such that the hydrocolloid support can be adhered to the flange in the correct position and, where the flange is provided with a similar release paper, the release paper of the flange then removed prior to mounting the ostomy bag upon the wearer.

Preferably, the hydrocolloid is semi-circular in shape, thus corresponding closely to the shape of the flange of the ostomy bag. Two hydrocolloid supports may be arranged in an opposed position about the flange, so that they extend around the complete circumference of the flange, thereby enabling the whole flange to be extended, where this is desired by a particular wearer.

The present invention will now be described, by way of example only, with reference to the accompanying drawings, in which like numerals are used throughout to indicate like parts, and of which:

Figure 1A is a plan view of a support in accordance with the present invention;

Figure 1B is a side elevation of the support of Figure 1A;

Figure 2 is a perspective view of the support of Figures 1A and 1B;

Figure 3 is a perspective view of the support of Figure 2, showing the release paper partially peeled back;

Figure 4 illustrates an ostomy bag fitted with a support in accordance with present invention; and

Figure 5 illustrates an ostomy bag fitted with two supports in accordance with present invention.

Referring to Figures 1A, 1B and 2, a support for an ostomy bag in accordance with the present invention, indicated generally as 1, comprises a layer of 0.6 mm thick Hyperflex™ hydrocolloid, an EU40 25µm thick polyurethane film backing 3 and a release paper divided by two cuts 4 and 5 into three sections 6a, 6b and 6c, the release paper being standard sterling coated paper. The properties of the hydrocolloid material 2 and

polyurethane film 3 are such that the support 1 is breathable when the release paper 6a, 6b, 6c is removed.

Figure 3 illustrates how the support 1 can be slightly flexed in the region of the slit 4 permitting the release paper to be held and peeled back. The release paper can similarly be removed starting at the slit 5.

Referring to Figure 4, there is illustrated a standard ostomy bag, illustrated generally as 7, comprising a receptacle portion 8, for receiving waste, and a flange 9. The flange 9 is formed of hydrocolloid material and has a release paper on its upper surface 10. In use the release paper is removed and the flange 9 centred on a stoma or wound of the wearer, such that fluid drains from the stoma or wound into the receptacle 8, via aperture 11 in the flange 9.

The support 1 of the present invention is placed in any desired position about the flange 9, and then slid partly behind the flange with the release paper 6a, 6b, 6c uppermost, as shown. In this position, starting at one of the slits 4 or 5, the release papers are peeled from the support 1 and the support adhered to the flange 9. Then the release paper (not shown) of the flange 9 is removed from the uppermost surface 10 and the flange 9 and support 1 simultaneously adhered to the wearer.

As shown in Figure 5, a number of supports in accordance with the invention may be used on an ostomy bag, either to completely surround the flange as shown in Figure 5, to further extend the flange in a particular direction, that is to say further than it could be extended by use of a single support, or a number of supports may be built up in depth so as



to account for any depression in the surface of the wearer adjacent a stoma. Although not illustrated, it is possible that supports of different sizes may also be provided.

The present invention has been illustrated by way of example only and further embodiments may be apparent within the scope of the appended claims.

**CLAIMS**

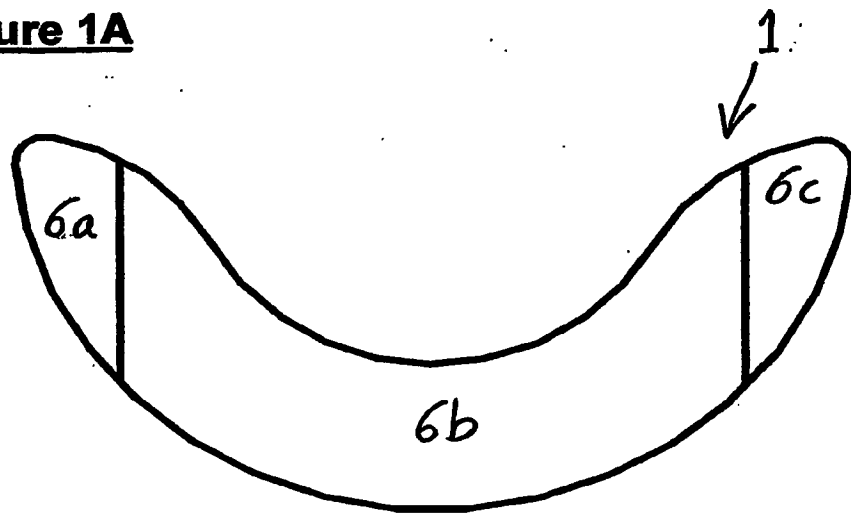
1. A support for an ostomy bag comprising a layer of hydrocolloid shaped to fit around and extend a portion of a flange of an ostomy bag.
2. A support as claimed in Claim 1, wherein the layer of hydrocolloid is self-adhesive on one side.
3. A support as claimed in Claim 2, wherein the said self-adhesive side of the hydrocolloid layer is covered by a release paper arranged to be removed prior to use.
4. A support as claimed in any preceding claim wherein the hydrocolloid layer is semicircular.
5. A support as claimed in any preceding claim, arranged to cooperate with a similar support to form a collar extending around the complete circumference of the flange.
6. A support for an ostomy bag substantially as hereinbefore described with reference to, and/or as illustrated in, one or more of the accompanying figures.

**ABSTRACT****A SUPPORT FOR AN OSTOMY BAG**

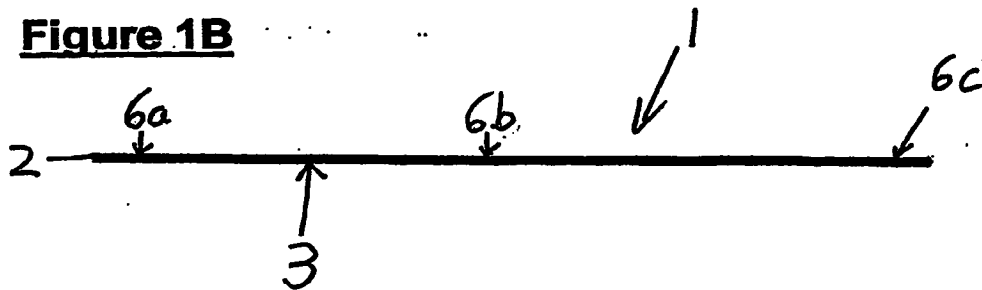
The present invention provides a support (1) for an ostomy bag (7), the support extending the flange of the ostomy bag to reduce the risk of leakage. The support (1) is formed of a hydrocolloid layer (2) shaped to fit around a flange (9) of the ostomy bag. The support can be fitted to the flange at any appropriate location enabling the flange to be supported at the point at which it is prone to failing on a particular wearer.

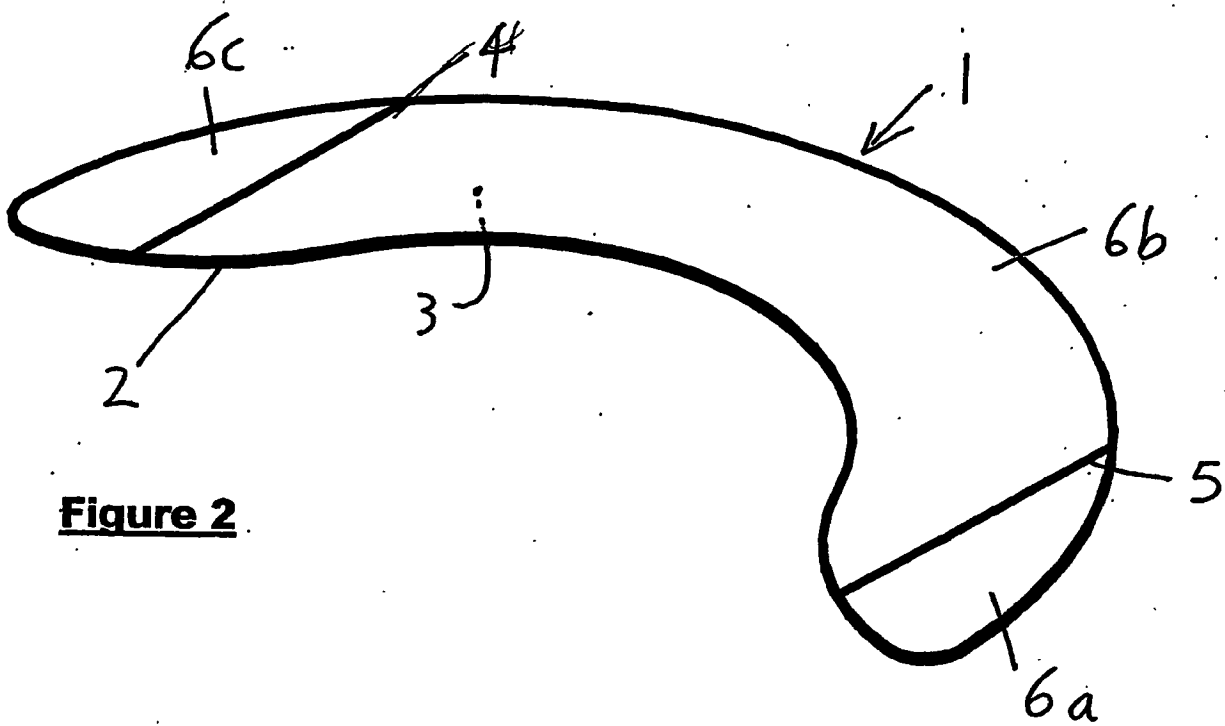
(Figure 4)

**Figure 1A**

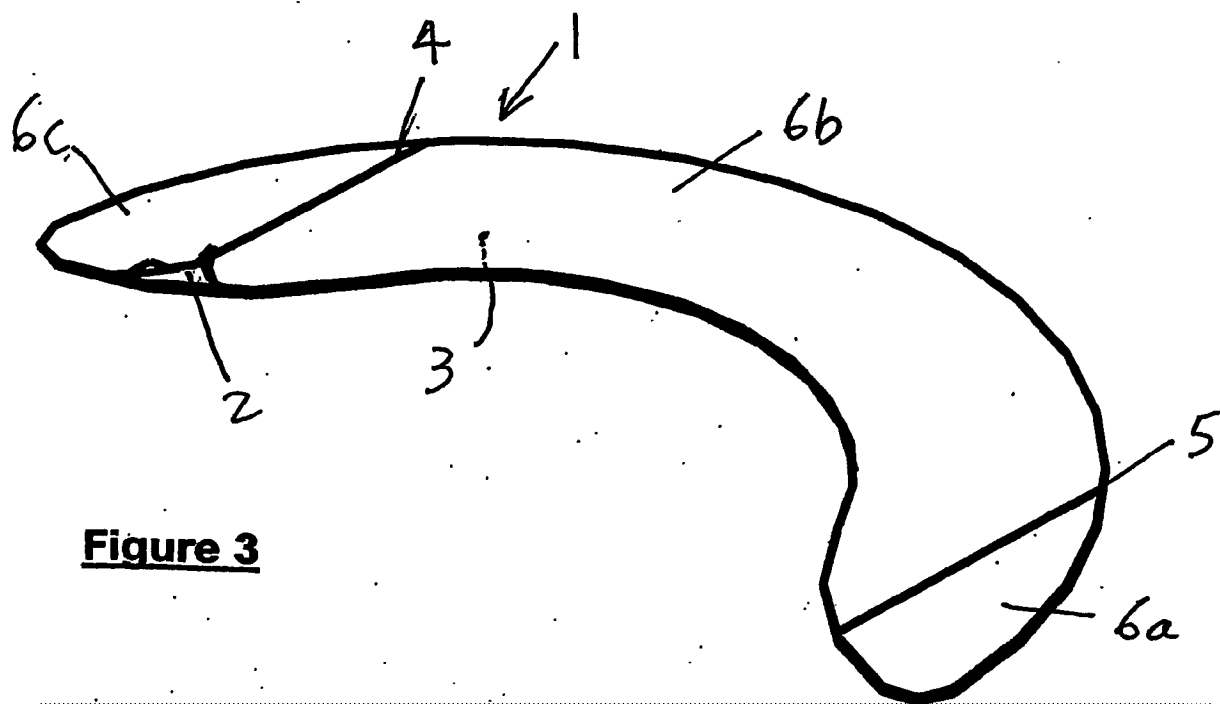


**Figure 1B**



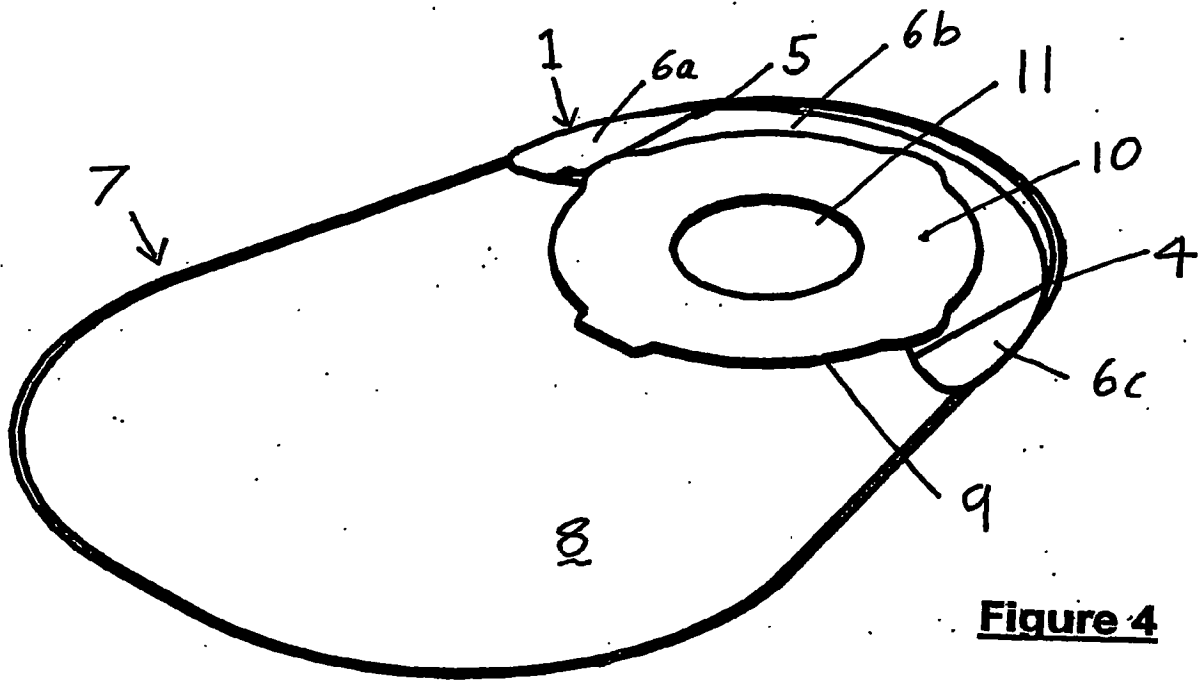


**Figure 2**

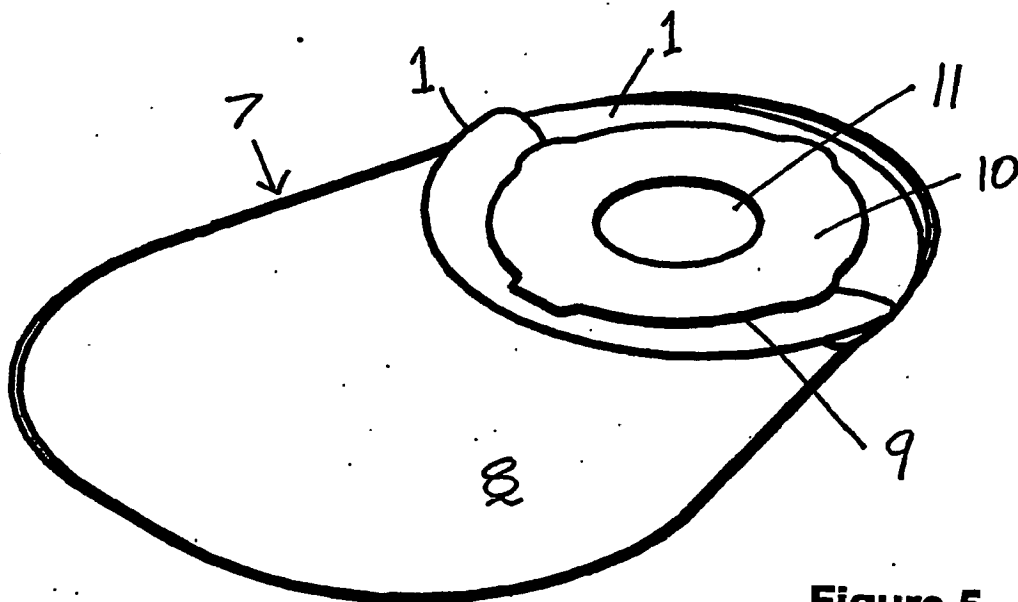


**Figure 3**

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**Figure 4**



**Figure 5**

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PCT Application  
**PCT/GB2004/000180**

